

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
CASE NO. 7:23-cv-1174

WILLIAM MARK CUMALANDER, on
behalf of himself and all others similarly
situated,

Plaintiff,

vs.

BLUECROSS BLUESHIELD OF
TENNESSEE, INC.

Defendant.

CLASS ACTION COMPLAINT

Plaintiff William Mark Cumalander, individually and on behalf of all others similarly situated, files this Class Action Complaint (the “Complaint”), pursuant to Rule 23 of the Federal Rules of Civil Procedure, asserting causes of action in law and equity for relief against Defendant BlueCross BlueShield of Tennessee, Inc.

I. INTRODUCTION

1. This is a class action on behalf of participants and beneficiaries of ERISA health benefit plans administered and/or insured by BlueCross BlueShield of Tennessee, Inc. (“BCBSTN”) who were denied benefits for proton beam radiation therapy (“PBRT”) to treat prostate cancer.

2. Plaintiff alleges that BCBSTN uniformly applied an arbitrary medical policy to deny claims for PBRT as experimental, investigational, and/or not medically necessary, despite PBRT being recognized for decades by the medical community as an established, safe, and effective standard of care for cancers, including prostate cancer.

II. PARTIES

3. Plaintiff William Cumalander is and was at all relevant times a resident of Wrightsville Beach, New Hanover County, North Carolina.

4. At all times relevant, Plaintiff was and remains a participant in an employee group health benefit plan (the “Plan”) governed by the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1001, et seq., and was entitled to health benefits pursuant to the ERISA Plan.

5. The Plan is insured and administered by BCBSTN. Attached hereto as **Exhibit A** is a true and correct copy of the applicable BCBSTN insurance policy for the Plan.

6. Plaintiff is informed and believes that Defendant BCBSTN is an insurance company with its principal place of business in Chattanooga, Tennessee, authorized to transact business and is transacting business in the Eastern District of North Carolina, and can be found in the Eastern District of North Carolina.

III. JURISDICTION AND VENUE

7. This action against Defendant arises under 29 U.S.C. §§1132(a), (c), (e), (f) and (g) of the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. §1001 et seq. This Court has jurisdiction over this action pursuant to 29 U.S.C. §1132(e)(1). Jurisdiction is predicated under these code sections as well as 28 U.S.C. §1331, as this action involved a federal question.

8. Venue is proper in this District and Division pursuant to 29 U.S.C. §1132(e)(2) because at all relevant times Plaintiff William Cumalander was a resident of Wrightsville Beach, New Hanover County, North Carolina, and some or all of the fiduciary breaches for which relief is sought occurred in this district. Defendant BCBSTN also maintains business activities in this district.

IV. GENERAL FACTUAL ALLEGATIONS

A. Proton Beam Radiation Therapy

9. Proton therapy is the most effective form of radiation therapy for many types of tumors. It destroys cancer cells by preventing them from dividing and growing, like conventional X-ray radiation. One of the major differences between proton therapy and conventional X-ray radiation is that protons deposit much of their radiation directly in the tumor and then stop. This allows patients to receive higher doses, which can be more effective, while reducing damage to healthy tissues that surround the tumor.

10. The physical properties of protons are different from the physical properties of X-rays. Protons are large, positively charged sub-atomic particles that penetrate matter to a finite depth. X-rays are electromagnetic radiation that penetrates completely through tissue. Protons can be conformed to release much of their energy at precise depths so they can target tumors inside the body, depositing much of their radiation exactly at the tumor site. X-rays release their maximum dose of radiation quickly after penetrating the skin, damaging healthy tissue and organs on their way to the tumor and again as they pass through the body beyond the tumor.

11. One of the goals of treatment is to deliver the proper dose of radiation to the tumor while limiting the dose received by the surrounding healthy tissue. To deposit the proper amount of energy into the tumor, X-rays must irradiate much of the healthy tissue in front of it, known as an “entrance dose,” and they continue to penetrate through the tumor and irradiate much of the healthy tissue behind it, known as an “exit dose.” To deliver the proper dose to a tumor, a radiation oncologist must “work around” the tumor by using multiple X-ray beams, delivering the highest dose where the beams intersect, but delivering low to medium “entrance” and “exit” doses to surrounding healthy tissue. In contrast, protons enter the patient at a low dose, then, at a precise depth, they deliver a large burst of energy. Immediately after this burst, they stop completely. To treat the entire tumor, additional protons are sent in at lower doses. In this way, protons completely irradiate the tumor while limiting the dose to the nearby healthy tissue. Proton treatment delivers a dose in a more accurate, more efficient way and spares more

of the surrounding healthy tissue. Since protons have a low “entrance dose” and essentially no “exit dose,” the volume of normal tissue receiving radiation with proton therapy is typically reduced by a factor of 2-3 when compared to even the most modern X-ray treatment plan.

12. Proton therapy allows for effective treatment of prostate cancer, while minimizing the radiation dose to vital functions, such as the gastrointestinal system or urinary tract.

13. In the late 1970s, imaging advancements coupled with the development of sophisticated computers and improved accelerator and treatment delivery technology made proton therapy more viable for routine medical applications, such as cancer treatment.

14. Proton therapy has been approved by the Federal Drug Administration since 1988 for the treatment of localized tumors and other conditions susceptible to treatment by radiation.

15. The first hospital-based proton-beam center in the United States was at the Loma Linda University Medical Center in Southern California, which began operation in 1990.

16. Currently in the United States, there are 42 proton therapy centers among 24 states.¹ There are currently no proton therapy centers in North Carolina, although one is under construction in Charlotte, North Carolina. Each of the 42 proton therapy centers in the United States offer proton therapy treatment for prostate cancer.

17. Many respected cancer facilities and providers treat prostate cancer with proton therapy, including but not limited to, University of Florida Proton Therapy Institute (where Plaintiff received treatment), Harvard Medical School/Massachusetts General Hospital, Northwestern University, Baptist Hospital’s Miami Cancer Institute, Loma Linda University, University of Maryland, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, MD Anderson Cancer Center, Penn Medicine, Johns Hopkins, and the Texas Center for Proton Therapy.

¹ <https://www.proton-therapy.org/map/>

18. Five of the top ten cancer centers in the United States according to the annual U.S. News & World Report rankings of the top cancer hospitals either have a proton center or are building a proton center.²

19. Over 200,000 patients have been treated with proton therapy. Prostate cancer is the most treated cancer type for proton therapy.

20. The University of Florida Health Proton Therapy Institute specifically lists prostate cancer as one of twelve identified cancers for which proton therapy is “a highly effective cancer treatment option.”

21. The medical community has found proton beam therapy radiation treatment to be a generally accepted standard of medical practice for the treatment of prostate cancer.

22. Other insurers, including Medicare, cover PBRT as a safe and effective prostate cancer treatment that is not “investigational.”

B. BCBSTN is an ERISA Fiduciary

23. The majority of health plans underwritten and/or administered by BCBSTN, including the Plan providing coverage for Plaintiff, are employee group health benefit plans governed by ERISA (“ERISA Plans”).

24. BCBSTN is an ERISA fiduciary, as defined by 29 U.S.C. § 1002(21)(A), with respect to Plaintiff’s Plan and the plans of all putative Class Members in that BCBSTN interprets and applies ERISA plan terms, makes coverage and benefit determinations under the ERISA plans within its discretion and may provide payment under the ERISA plans to participants, beneficiaries, and their providers. Accordingly, BCBSTN was required to comply with the requirements ERISA imposes on fiduciaries.

25. At all relevant times alleged herein, BCBSTN acted as both a named and functional fiduciary with respect to the specific issues alleged herein.

² <https://health.usnews.com/best-hospitals/rankings/cancer>

26. The health benefit plans administered by BCBSTN are either (1) insured by an insurance policy issued by BCBSTN, or (2) self-funded by the employer through a trust or assets.

27. With respect to insured plans, including Plaintiff's, BCBSTN both administers the plan by making all benefit determinations and pays the benefits out of its own assets.

28. With respect to self-funded plans, BCBSTN serves as claims administrator for the plan and the plan sponsor or employer is responsible for providing the funding for BCBSTN to issue benefit payments.

29. When processing benefits for a self-funded plan, BCBSTN makes all benefit determinations and authorizes benefit checks to be issued out of bank accounts that BCBSTN controls and is fully responsible for processing the health claims and making the determination whether to issue the check from these accounts.

30. Whether an ERISA plan is fully insured or self-funded, BCBSTN is the proper party for Plaintiff, and the putative Class, to seek relief from because BCBSTN made all the relevant benefit determinations for the ERISA plans.

C. BCBSTN's Proton Beam Therapy Medical Policy

31. BCBSTN drafted, adopted, applied, and continues to apply Proton Beam Therapy Medical Policy ("BCBSTN Medical Policy") to requests for coverage, requests for prior approval, and claims for benefits for proton beam therapy.

32. BCBSTN Medical Policy was most recently reviewed before Plaintiff's claim, on May 13, 2021.

33. The BCBSTN Medical Policy provides sources from 13 journal articles and only one pertains to prostate cancer and was dated from 2016.

34. The BCBSTN Medical Policy states that PBRT is investigational for prostate cancer.

35. The BCBSTN Medical Policy states that for the treatment of localized prostate cancer, PBRT has not been shown to be superior to conventional radiation therapy.

36. BCBSTN Medical Policy is unsupported by the standard of care for treatment of prostate cancer in the medical community.

37. BCBSTN denied Plaintiff's claims for PBRT based upon the BCBSTN Medical Policy.

D. BCBSTN Plan Definition of Investigational

38. The Plan provides the following definition of Investigational:

Investigational – The definition of Investigational is based on BlueCross's technology evaluation criteria. Any technology that fails to meet ALL of the following four criteria is considered to be Investigational.

- a. The technology must have final approval from the appropriate governmental regulatory bodies, as demonstrated by:
 - i. This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the use of the technology.
 - ii. Any approval that is granted as an interim step in the U.S. Food and Drug Administration's or any other federal governmental body's regulatory process is not sufficient.
- b. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes, as demonstrated by:
 - i. The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
 - ii. The evidence should demonstrate that the technology could measure or alter the physiological changes related to a disease, injury, illness or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
- c. The technology must improve the net health outcome, as demonstrated by:
 - i. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- d. The improvement must be attainable outside the Investigational settings, as demonstrated by:
 - i. Reviewing the criteria above, the medical policy panel will consider physician specialty society recommendations, the view of prudent medical Practitioners practicing in relevant clinical areas and any other relevant factors.

The Medical Director, in accordance with applicable ERISA standards, shall have discretionary authority to make a determination concerning whether a

service or supply is Investigational. If the Medical Director does not Authorize the provision of a service or supply, it will not be a Covered Service. In making such determinations, the Medical Director shall rely upon any or all of the following, at his or her discretion:

- a. Your medical records; or
- b. The protocol(s) under which proposed service or supply is to be delivered; or
- c. Any consent document that You have executed or will be asked to execute, in order to receive the proposed service or supply; or
- d. The published authoritative medical or scientific literature regarding the proposed service or supply in connection with the treatment of injuries or illnesses such as those experienced by You; or
- e. Regulations or other official publications issued by the FDA and Department of Health and Human Services (HHS); or
- f. The opinions of any entities that contract with the Plan to assess and coordinate the treatment of Members requiring non-experimental or Investigational services; or
- g. The findings of the BlueCross BlueShield Association Technology Evaluation Center or other similar qualified evaluation entities.

39. BCBSTN's application of its Proton Beam Medical Policy resulted in the denial of PBRT coverage for Plaintiff and Members of the Class he seeks to represent (as defined below) violated the terms of the relevant plans and BCBSTN's fiduciary obligations under ERISA.

40. The Plan definition of an investigational treatment is in conflict with BCBSTN's Medical Policy. BCBSTN's Medical Policy imposes an additional requirement for coverage by requiring that the requested treatment must be *superior* to an alternative treatment.

41. BCBSTN systematically relied on its internally developed Proton Beam Medical Policy to inappropriately justify applying more restrictive coverage guidelines than allowed for under the plain language of the relevant Employer Plan.

42. Plaintiff's Employer Plan required BCBSTN to cover treatment that is "[w]ithin generally accepted standards of medical practice for the Member's medical condition." Plaintiff clearly established that PBRT is within the generally accepted standards of medical practice of his medical condition, *i.e.* prostate cancer, and therefore BCBSTN's decision to deny benefits for PBRT was contradictory to the Plan language.

V. PLAINTIFF'S INDIVIDUAL FACTUAL ALLEGATIONS

A. Plaintiff's Claims for PBRT and BCBSTN's Denials

43. Plaintiff was diagnosed with prostate cancer in September 2022. He consulted with physicians at University of Florida Proton Therapy Institute, including Dr. William Mendenhall, for treatment recommendations.

44. Dr. Mendenhall recommended that Plaintiff undergo PBRT as an alternative to IMRT for many reasons including PBRT reduces the probability of long-term side effects (*i.e.* incontinence, bleeding/irritation, obstruction, strictures) and post-treatment complications.

45. Plaintiff requested BCBSTN approve benefits for his PBRT at University of Florida Proton Therapy Institute.

46. In a September 20, 2022 letter, BCBSTN denied benefits for Plaintiff's PBRT, claiming treatment was "investigational per the BlueCross BlueShield of Tennessee Proton Beam Medical Policy unless there are unique circumstances applicable to a specific member that would make use of the proton beam therapy medically appropriate." BCBSTN cited the American Society for Radiation Oncology (ASTRO) Model Policy and the National Comprehensive Cancer Network (NCCN) Panel. BCBSTN claimed PBRT remains investigational for the treatment of prostate cancer.

47. Dr. Mendenhall requested a peer review with BCBSTN.

48. In a letter dated October 10, 2022, BCBSTN again denied benefits following the peer review. BCBSTN claimed there was lack of significant clinical trials published in peer reviewed journals supporting the benefits of PBRT compared to conventional photon beam radiation therapy.

49. Dr. Mendenhall requested an expedited appeal with BCBSTN.

50. In a letter dated October 14, 2022, BCBSTN again denied benefits following the expedited appeal, claiming PBRT "has not proven to yield superior clinical outcomes" compared to standard treatment options including IMRT, treatment is not supported by ASTRO Model policy, and according to its Proton Beam Therapy medical policy.

51. On October 14, 2022, Dr. Mendenhall submitted a written request for an expedited external appeal. Dr. Mendenhall wrote that PBRT is recommended because it reduces long-term side effects and long-term complications. Dr. Mendenhall wrote that BCBSTN “is not considering the long-term consequences of not treating Mr. Cumalander with the best available care options. PBT provides the best chance of reducing post-treatment complications – all reasons for approving PBT, especially with a favorable prognosis with treatment.” Dr. Mendenhall provided the following evidence in support of PBRT:

- BCBSTN’s medical policy is incomplete because it lists 23 references regarding proton therapy and only three pertain to prostate cancer. Dr. Mendenhall provided 79 references to trials and case studies which support PBRT for prostate cancer.
- Evidence showing the superiority of PBRT versus IMRT. Dr. Mendenhall provided comparisons between PBRT and IMRT for various structures (*i.e.* bladder, rectum, small bowel) with each comparison showing PBRT as the better plan.
- PBRT has decreased mortality compared to photon therapy by 24.4%.
- PBRT prevents grade 3 and 4 toxicities and complications by targeting the prostate alone with minimal exit dose thus reducing unnecessary radiation by 10% to his bowel and 15-35% to his bladder.
- PBRT prevents hip fractures and radiation to the femur which would be in the path of the treatment fields. With PBRT, unnecessary irradiation and weakening of the femur is minimized.
- ASTRO Model Policy supports the medical necessity of PBRT to prevent complications and toxicities. ASTRO Medical Policy for PBRT states that PBRT is medically necessary to spare the surrounding normal tissue when it cannot be effectively achieved with photon-based radiotherapy. A photon

based technique would increase the probability of tissue toxicity by exceeding the dose to Plaintiff's large and small bowel, bladder, and rectum.

52. Dr. Mendenhall concluded that PBRT "is medically necessary and the superior care for Mr. Cumalander's prostate cancer for several reasons:

1. Reduces the probability of acute and late urinary toxicity associated with intact prostate radiation therapy.
2. Proton beam therapy will decrease Mr. Cumalander's risks of gastrointestinal (GI) toxicities such as diarrhea, by sparing his rectum by 10%.
3. Proton beam therapy will reduce urinary toxicity rates for Mr. Cumalander by 15-35%, thereby alleviating the potential for additional urinary symptoms aside from the urinary stream and frequent urination he currently experiences.
4. Proton beam therapy will minimize irradiation to Mr. Cumalander's femur, and as a result, may potentially prevent radiation-induced hip fractures that could lead to catastrophic outcomes."

53. In a letter dated October 18, 2022, BCBSTN denied the expedited external appeal, claiming treatment is investigational and citing the same reasons – verbatim in parts – as its October 14, 2022 denial letter.

54. Notwithstanding BCBSTN's denial of coverage, Plaintiff proceeded to have PBRT, with very positive results, and paid out-of-pocket for the cost of treatment.

55. The superiority and efficacy of PBRT administered to Plaintiff is evidenced by his pre-treatment PSA readings of 24 and post-treatment readings of 3.5 (readings between 0.00 and 4.0 are considered normal). Plaintiff experienced few if any toxicities from PBRT and has fully recovered less than 4 months after treatment.

56. Upon information and belief, Plaintiff's superior recovery is consistent with the medical evidence supporting PBRT as stated by Dr. Mendenhall; and, Plaintiff further alleges, upon information and belief, that the Class Members would have had the same or similar superior results but for Defendant's wrongful denial of benefits.

57. Plaintiff exhausted all administrative remedies required under ERISA and performed all duties and obligations on his part to be performed, and this claim is ripe for judicial review pursuant to 29 U.S.C. § 1132.

B. BCBSTN's Violations of ERISA

58. As the claims administrator responsible for interpreting and administering the Employer Plan and similar BCBSTN plans issued nationwide, and vested with responsibility for making final benefit determinations, BCBSTN is an ERISA fiduciary.

59. As an ERISA fiduciary, BCBSTN was required to discharge its duties consistent with 29 U.S.C. § 1104, which requires (among other things) that it do so “solely in the interest of the participants and beneficiaries” and for the “exclusive purpose” of “providing benefits to participants and their beneficiaries” and paying reasonable expenses of administering the plan. It must do so with “care, skill, prudence, and diligence” and in accordance with the terms of the plans it administers. BCBSTN did not satisfy these requirements of a fiduciary.

60. BCBSTN failed to satisfy its duties when it prepared and applied the BCBS Proton Beam Therapy Medical Policy (the “Medical Policy”) because the Medical Policy relied on incomplete and outdated medical evidence, ignored medical evidence supporting PBRT as the standard of care for treatment of prostate cancer, and unreasonably concluded that PBRT was investigational.

61. BCBSTN compounded its fiduciary breach by relying upon the Medical Policy to deny health claims submitted by Plaintiff and Class Members in contravention of the terms of their BCBSTN plans.

62. BCBSTN did not act “solely in the interests of the participants and beneficiaries” when it denied coverage for PBRT as investigational when the evidence submitted to BCBSTN demonstrated that PBRT is not investigational for treatment of prostate cancer and is a standard of care in the medical community.

63. In violating its fiduciary duties, BCBSTN elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining

whether to cover PBRT for prostate cancer. By promulgating and applying its Medical Policy, BCBSTN sacrificed the interests of insureds like Plaintiff and the Class Members so that it could artificially decrease the number and value of claims both that it was forced to pay out of its own assets and that it asked its self-funded employer-sponsor customers to pay and prioritized the assets of its employer-sponsor customer. BCBSTN also advanced its own interests in retaining and expanding its business with such customers.

64. BCBSTN's breach of its fiduciary duties by improperly denying benefits for PBRT, resulted in Plaintiff paying \$43,185.00 to receive the PBRT prescribed to him by his treating radiation oncologists. Because PBRT provided the best, safest, and most effective course of treatment for Plaintiff and many others, he now brings this action on behalf of the Class Members, as well.

65. BCBSTN has unqualified medical directors with no experience or training in the context of radiation oncology, PBRT, and/or who are not board certified in the requisite medical specialty, adjudicate Members' claims and render boilerplate adverse benefit determinations.

66. BCBSTN's use of unqualified medical reviewers is a systemic, institutional abdication of its duty to screen, conduct background checks, review available public records through state medical licensing boards, and conduct meaningful interviews of qualified candidates before employing candidates as medical directors who are charged with rendering life and death decisions for Members who seek life-saving treatment under their respective plans, and violates ERISA regulations and case precedent.

67. By placing this Medical Policy into the hands of medical directors who are not qualified to render opinions as to the medical necessity of PBRT, who lack the education, training and experience to appreciate factors in a given case that indicate the medical necessity for PBT, who are unaware of contemporary medical evidence in the requisite specialty indicating the medical necessity for PBRT, and who follow the inadequate policies and procedures for clinical review, BCBSTN categorically wrongfully denies all prior approval requests and claims for PBRT for prostate cancer.

VI. CLASS ACTION ALLEGATIONS

68. Plaintiff brings this action individually and on behalf of all others similarly situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23.

69. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of a “PBRT Class,” defined as follows:

All persons covered under ERISA-governed plans, administered or insured by BCBSTN, whose pre-service or post-service requests to BCBSTN for benefits for proton beam radiation therapy for the treatment of prostate cancer were denied at any time within the applicable statute of limitations, or whose requests to BCBSTN for PBRT will be denied in the future, based upon a determination by BCBSTN that PBRT is not medically necessary or is experimental, investigational, or unproven.

70. The definition of “investigational” contained in Plaintiff’s employer Plan and relied upon by BCBSTN in denying coverage for Plaintiff for PBRT is the same or substantially similar to, and is interpreted by BCBSTN as having the same meaning as, comparable definitions and exclusions included in the BCBSTN plans applicable to all Class Members.

71. The PBRT Class excludes (a) BCBSTN, including any entity or division in which BCBSTN has a controlling interest, as well as its agents, representatives, officers, directors, employees, trustees, and other entities related to, or affiliated with BCBSTN, (b) Class Counsel, and (c) the Judge to whom this case is assigned and any Members of the Judge’s staff or immediate family.

72. Plaintiff and the Class Members reserve the right under Federal Rules of Civil Procedure Rule 23(c)(1)(C) to amend or modify the class to include greater specificity, by further division into subclasses, or by limitation to particular issues.

73. This action has been brought and may be properly maintained as a Class Action under the provisions of Federal Rules of Civil Procedure Rule 23 because there is a well-defined community of interest in the litigation and the proposed class is ascertainable.

A. Numerosity

74. The potential Members of the proposed class as defined are so numerous that joinder of all the Members of the proposed class is impracticable.

75. While the precise number of proposed Class Members has not been determined at this time, Plaintiff is informed and believes that there are a substantial number of individuals covered under plans insured or administered by BCBSTN who have been similarly affected.

76. Prostate cancer accounts for more than 25% of new cancer cases diagnosed in men with an estimated 248,530 new cases of prostate cancer diagnosed in 2021.³

77. Breast cancer and prostate cancer are most frequently treated with PBRT.⁴

78. BCBSTN reports a total of 3,300,000 members.⁵

79. The PBRT Class is ascertainable because its Members can be readily identified using BCBSTN's claims data. PBRT therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by the American Medical Association. Accordingly, Class Members can be readily and objectively ascertained through use of records maintained by BCBSTN.

80. Finally, PBRT Class Members are dispersed geographically throughout the United States such that joinder of all Members is impracticable.

B. Commonality

81. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers predominate over questions affecting only individual Class Members. These include, without limitation:

- a. Whether PBRT therapy is an "investigational" service or treatment for prostate cancer under Plans insured and/or administered by BCBSTN;
- b. Whether BCBSTN categorically applied its Proton Beam Therapy Medical

³ Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin*. 2021;71(1):7–33.

⁴ <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791568>

⁵ <https://bcbstnews.com/mediaresources/bluecross-by-the-numbers/>

Policy to deny coverage to PBRT Class Members;

- c. Whether PBRT Class Members' claim denials were based in whole or in part on the BCBSTN Proton Beam Therapy Medical Policy;
- d. Whether the criteria set out in the BCBSTN Proton Beam Therapy Medical Policy conflicts with Class Members' Plans;
- e. Whether the application of the BCBSTN Proton Beam Therapy Medical Policy to Class Members' claims was a breach of BCBSTN's fiduciary duties under ERISA;
- f. Whether PBRT Class Members are entitled to the relief sought if Plaintiff establishes liability.

C. Typicality

82. Plaintiff's claims are typical of the claims of PBRT Class Members because Plaintiff was a participant in an ERISA Plan administered by BCBSTN, submitted a claim for coverage of PBRT for treatment of his prostate cancer, and, like other PBRT Class Members, BCBSTN denied his claim for PBRT based on the flawed, out-of-date, and artificially restrictive PBRT Medical Policy.

D. Adequacy of Representation

83. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff's interests do not conflict with the interests of the Members of the Class. Further, Plaintiff has retained counsel who are competent and experienced in complex class action litigation, and Plaintiff and his counsel intend to prosecute this action vigorously on behalf of the Class Members and have the financial resources to do so. Neither Plaintiff nor his counsel has any interest adverse to those of the Class Members.

E. Superiority

84. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(1) because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications that could establish incompatible standards of conduct for BCBSTN.

85. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because by applying a uniform Medical Policy treating PBRT as “investigational (experimental),” BCBSTN has acted and refused to act on grounds that apply generally to the Class, thereby requiring the Court’s imposition of uniform relief to ensure compatible standards of conduct towards Class Members, and making final injunctive relief or corresponding declaratory relief appropriate respecting the proposed Class as a whole.

86. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(3) because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. Questions of law and fact common to the Class Members predominate over any questions affecting only individual Members.

87. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class Members is impracticable.

88. Further, because the unpaid benefits denied Class Members are small relative to the expense and burden of individual litigation, it would be impossible for the Members of the Class to redress individually the harm done to them, such that most or all Class Members would have no rational economic interest in individually controlling the prosecution of specific actions, and the burden imposed on the judicial system by individual litigation by even a small fraction of the Class would be enormous, making class adjudication the superior alternative under Fed. R. Civ. P. 23(b)(3)(A) .

89. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties’ resources, and far more effectively protects the rights of each Class Member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

VII. FIRST CLAIM FOR RELIEF

For Denial of Benefits on Behalf of Plaintiff and the Class

90. Plaintiff individually and on behalf of the Class members repeats and re-alleges each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.

91. This count is brought pursuant to 29 U.S.C. § 1132(a)(1)(B).

92. BCBSTN wrongfully denied Plaintiff and the Class Members' claims for PBRT at a time when BCBSTN knew, or should have known, that Plaintiff and the Class Members were due those benefits under the terms of their respective plans.

93. BCBSTN wrongfully denied Plaintiff and the Class Members' claims for PBRT by unreasonably relying upon its Medical Policy that was flawed, out-of-date, and artificially restrictive.

94. BCBSTN failed to provide prompt and reasonable explanations of the bases relied on under the terms of the plan documents, in relation to the applicable facts and plan provisions, for the denial of Plaintiff's and the Class Members' claims for medical benefits.

95. BCBSTN failed to properly and adequately investigate the merits of Plaintiff's and the Class Members' medical claims and failed to provide them with a full and fair review pursuant to 29 C.F.R. §2560.503-1 (h)(3)(iii) by failing to consult with health care professionals who have appropriate training and experience in the field of medicine involved in the medical judgment.

96. BCBSTN failed to thoroughly and independently evaluate both Plaintiff's and the Class Members' medical records prior to issuing their denials of their claims and their appeals and failed to provide them with a copy of the internal guidelines relied upon in making the adverse benefit determination, in violation of 29 C.F.R. §2560.503-1 (g)(v)(A).

97. Plaintiff is informed and believes that BCBSTN wrongfully denied his claims for medical benefits by other acts or omissions of which he is presently unaware, but which may be discovered in this future litigation and which he will immediately make BCBSTN aware of once said acts or omissions are discovered by him.

98. Following the denial of Plaintiff's claims for medical benefits under the Plan, he exhausted all administrative remedies required under ERISA, and he performed all duties and obligations on his part to be performed.

99. Plaintiff and Class Members have been harmed by BCBSTN's improper benefit denials because they were deprived of health benefits they were owed.

100. Plaintiff and Class Members seek the relief identified below to remedy this claim.

VIII. SECOND CLAIM FOR EQUITABLE RELIEF

For Declaratory, Injunctive and Other Equitable Relief, and Attorneys' Fees

Pursuant to ERISA 29 U.S.C. §§ 1132(a)(3), (g)

101. Plaintiff individually and on behalf of the Class Members repeats and re-alleges each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.

102. BCBSTN acts as an ERISA fiduciary with respect to the administration and claims decisions of the group health plans within the meaning of 29 U.S.C. §§ 1109(a) and 1002(21)(A). With respect to these plans, BCBSTN exercises discretionary authority or control respecting management of the plans, or exercise authority or control respecting management or disposition of the plans' assets. BCBSTN has the authority, and actually exercised the authority, to fund the plans, make decisions on claims for benefits and appeals thereof, and write checks for benefits.

103. BCBSTN has categorically and improperly denied requests for PBRT to treat prostate cancer, as alleged above.

104. In acting and failing to act as described above, BCBSTN has breached its fiduciary duty.

105. 29 U.S.C. § 1109(a) provides that "[a]ny person who is a fiduciary with respect to a plan who breaches any of the responsibilities, obligations, or duties imposed upon fiduciaries by this subchapter shall be personally liable."

106. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), BCBSTN is required to discharge its duties "solely in the interests of the participants and beneficiaries" and

for the “exclusive purpose of providing benefits to participants and their beneficiaries” and pay “reasonable expenses of administering the plan.”

107. BCBSTN must do so with reasonable “care, skill, prudence, and diligence” and in accordance with the terms of the plans it administers. BCBSTN must conform its conduct to a fiduciary duty of loyalty and may not make misrepresentations to its insureds.

108. BCBSTN violated these duties by adopting and implementing a Proton Beam Therapy Medical Policy to deny coverage for PBRT based on investigational exclusions under its plans, when such a finding was contrary to generally accepted practices and to the terms of the plans. BCBSTN ignored current scientific evidence and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the investigational exclusion to PBRT.

109. In doing so, BCBSTN did not act “solely in the interests of the participants and beneficiaries” for the “exclusive purpose” of “providing benefits.” BCBSTN did not utilize the “care, skill, prudence, and diligence” of a “prudent man” acting in a similar capacity. BCBSTN did not act in accordance with the terms of the Employer Plan and other BCBSTN plans, all of which contain such an investigational exclusion.

110. BCBSTN elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incomplete and outdated Medical Policy, BCBSTN artificially decreased the number and value of covered claims thereby benefiting itself and its corporate affiliates and clients at the expense of claimants.

111. BCBSTN did not act “solely in the interests of the participants and beneficiaries” when it denied coverage for PBRT. Rather, upon information and belief, BCBSTN denied coverage for PBRT to treat prostate cancer despite evidence establishing PBRT was not investigational for treatment of prostate cancer.

112. BCBSTN’s decision to apply its Medical Policy without any recent clinical developments that acknowledge that PBRT is no longer investigational, demonstrates that

BCBSTN arbitrarily applied the Medical Policy to Plaintiff's claim and continues to arbitrarily apply the Medical Policy to Class claims.

113. Plaintiff and Class Members have been harmed by BCBSTN's breaches of fiduciary duty because their claims have been subjected improperly to investigational exclusion, leading to denials of coverage for PBRT, when PBRT is a Covered Service within the definition of the BCBSTN plans.

114. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiff and the Class Members seek equitable and remedial relief as follows:

- a. An injunction compelling BCBSTN to: (1) retract their categorical denials of PBRT for the treatment of prostate cancer; (2) provide notice of said determinations in the form and manner required by ERISA to all BCBSTN subscribers/members who have had requests for PBRT to treat prostate cancer denied; (3) provide for the re-review of all such improperly denied claims; and (4) revise and update its Medical Policy to be consistent with current medical literature, research, studies, trials, and generally accepted standards of care.
- b. An accounting and disgorgement by BCBSTN of any profits made by BCBSTN from the monies representing the improperly denied claims and disgorgement of any profits accrued by BCBSTN by denying PBRT requests for the treatment of prostate cancer.
- c. Such other equitable and remedial relief as the Court may deem appropriate; and
- d. Attorneys' fees in an amount to be proven at the time of trial.

IX. CLAIM FOR ATTORNEYS' FEES & COSTS

115. Plaintiff seeks an award of his reasonable attorneys' fees incurred and to be incurred in the prosecution of this claim. He is entitled to recover those fees, together with his costs of court, pursuant to 29 U.S.C. §1132(g).

X. PRAYERS FOR RELIEF

116. Plaintiff individually and on behalf of the Class Members respectfully prays that upon trial of this matter or other final disposition, this Court find in his favor and against BCBSTN and issue judgment against BCBSTN as follows:

- a. An Order certifying the proposed Class, appointing Plaintiff to represent the proposed Class, designating Plaintiff's counsel as Class Counsel, and approving a service award for Plaintiff;
- b. An Order finding that Plaintiff and the proposed Class are entitled to recoupment of benefits due under the BTBSTN plans;
- c. An Order declaring that BCBSTN's practices described herein violate ERISA and its ERISA-based fiduciary duties, responsibilities, and obligations;
- d. An Order requiring BCBSTN to reprocess Plaintiff and Class Members' claims for PBRT to treat prostate cancer in accordance with ERISA;
- e. An Order requiring BCBSTN to revise and update its Medical Policy to be consistent with current medical literature, research, studies, trials, and generally accepted standards of medical care;
- f. An Order requiring BCBSTN to create a common fund out of which it will make payment, with interest, of any unpaid benefits to Plaintiff and the Member Class;
- g. Payment of health benefits due to Plaintiff and the Member Class under BCBSTN's applicable plans;
- h. Injunctive relief, as described above;

- i. Monetary damages in an amount to be proved at trial;
- j. Disgorgement of all profits unjustly retained by BCBSTN as the result of its wrongful denials of PBRT for the treatment of prostate cancer;
- k. Other appropriate equitable relief as permitted by law, equity, and the federal statutory provisions set forth herein, including but not limited to surcharge, constructive trust, restitution, equitable estoppel, and/or any other appropriate remedial relief;
- l. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorneys' fees incurred in pursuing this action;
- m. Payment of prejudgment interest at a rate of at least the North Carolina legal rate of 8% and post-judgment interest as allowed for under ERISA; and
- n. For such other equitable, remedial, and further relief as the Court deems just and proper.

This the 20th day of July, 2023.

/s/Norris A. Adams, II

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